UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TED DAVISON, WILLIAM GOULD, AND RAY LENCI, Individually and On Behalf of All Others Similarly Situated, Plaintiffs, vs. VENTRUS BIOSCIENCES, INC., DR. RUSSELL H. ELLISON, and DAVID J. BARRETT, Defendants.	Index No.: 13 CIV 3119-RMB

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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INTRODUCTION

In seeking to vindicate their Consolidated Amended Class Action Complaint ("CAC"), plaintiffs maintain that they have obtained telling information from confidential witnesses ("CWs") who open a window to the alleged fraud. On inspection, the information provided by these CWs falls far short of suggesting any falsehood or deceit, and in no way satisfies the heightened standard for pleading scienter or a false statement under the PSLRA. The gravamen of the CAC, as recapitulated in plaintiffs' opposition brief ("Opp."), appears to be that defendants' optimistic statements in anticipating the results of a Phase III trial for VEN 309 could not reasonably be justified since the promising results of an earlier Phase IIb trial had been based on a very small sample size. This theory cannot stand. The sample size of the earlier Phase IIb trial was fully disclosed to the investing public, thereby negating any possibility of fraud, and, in any event, plaintiffs have not alleged – and cannot allege – that the Phase IIb sample size was unusual or in any way contrary to regulatory or industry standards for a Phase II trial.

Moreover, the CAC cites no statement made by any individual defendant – nor any contemporaneous email, memorandum, or other document circulated within Ventrus – revealing an intent to commit fraud. Indeed, it fails to allege even a single conversation between any defendant and a CW. In the face of these obvious shortcomings, the CAC reduces to nothing more than conclusory allegations, unsupported by any specific indicia of fraud, in circumstances where it is clear that defendants themselves held onto and even increased their financial stake in Ventrus, thereby suffering major economic losses along with their shareholders when the VEN 309 Phase III trial yielded disappointing results. It is not in society's interest to deter drug companies from pursuing Phase III trials by permitting them to be sued for fraud simply on the theory that they were too confident in their Phase II results. Indeed, doing so would "choke off

the lifeblood of innovation in medicine by fueling frivolous litigation . . . ." *Cozzerelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 627 (4th Cir. 2008). This case should be dismissed.

I. THE CWS HAVE NOT IDENTIFIED A SINGLE FALSE STATEMENT AND PROVIDE NO EVIDENCE OF SCIENTER

It is undisputed that CW1 was not employed at Ventrus during the Class Period and thus can provide no insight about defendants' state of mind at the time that the fraud allegedly occurred.[1] Plaintiffs emphasize their allegation that, before the Class Period, CW1 "worked directly with" defendant Ellison (Opp. at 12), even though the defense has pointed out that, in fact, Dr. Ellison did not work at Ventrus at the time (Op. Brief at 12). Yet, even if one accepts plaintiffs' allegation, nowhere does the CAC identify a single statement allegedly made by defendant Ellison or by anyone else at Ventrus to CW1 – at any point in time – let alone any statement indicative of an intent to defraud. CW1 provides no information about what anyone else at Ventrus said or thought about the VEN 309 program. He offers his own opinions, in retrospect, about the sample size of the Phase IIb trial, but does not describe even a single conversation in which that issue was raised at the time he was employed at Ventrus.[2] The same is true of his opinions regarding the Special Protocol Assessment ("SPA"), which Ventrus pursued for the most part after he had left the company in March 2009: the CAC identifies no conversation concerning an SPA for VEN 309 in which CW1 took part.

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[1] CW allegations "must be discounted" (*In re MRU Holdings Sec. Litig.*, 769 F. Supp. 2d 500 516 (S.D.N.Y. 2011)), particularly where, as here, they are uncorroborated by "other facts" (*Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)).

[2] Plaintiffs cite no authority for the proposition that because CW1 was a Chief Medical Officer, he was "qualified to state facts or express opinions regarding the Company's drug trials." (Opp. at 13.) To the contrary, CW1 appears to lack even a basic understanding of statistical analysis in clinical trials. Indeed, he ignores that "[a]nalyzing data from small samples may require more stringent assumptions, ***but there is no fundamental difference in the meaning of confidence intervals and p-values***." Fed. Judicial Ctr., *Reference Manual on Scientific Evidence*, 126 n.145 (2d ed. 2000) (emphasis added). (*See also* Op. Brief at 5 n.4, 18 n.13.)

CW2 receives less emphasis in plaintiffs' opposition brief, perhaps because she has even less to offer than CW1. Her statements, even if credited as true, touch solely upon whether Ventrus was "cheap" when it came to making expenditures on its clinical trials (Opp. at 6), an issue distinct from any alleged fraud. She reports no conversation with anyone at Ventrus and no statement by any Ventrus officer or employee. She thus offers no evidence from which a fraudulent state of mind might be inferred. Perhaps this is because she was never employed at Ventrus: she was a contract employee hired by an organization that was reporting the results of its work to Ventrus. It is not alleged that she ever had any direct contact with anyone at Ventrus itself. *See In re Zumiez Inc. Sec. Litig.*, 2009 WL 901934, at *8 (W.D. Wash. Mar. 30, 2009) (CW's allegations cannot be relied on where CW was not in a position to analyze the company from a sufficient perspective).

CW3 is mentioned nowhere in plaintiffs' opposition brief.

II. PLAINTIFFS' FURTHER ATTEMPTS TO PLEAD SCIENTER ALSO FAIL

Plaintiffs maintain that Ventrus was motivated by a desire to raise capital, and that its officers were motivated by the prospect of financial bonuses. (Opp. at 14-15.) These allegations fail to distinguish Ventrus and its officers from any other company, and it is well settled that they are insufficient as a matter of law to plead scienter. *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001) ("Motives that are generally possessed by most corporate directors and officers do not suffice . . . ."); *In re Anonyx Sec. Litig.*, 2009 WL 812244, at *4 (S.D.N.Y. Mar. 27, 2009) (company's plan to raise capital does not give rise to inference of scienter); *In re Portal Software, Inc. Sec. Litig.*, 2005 WL 1910923, at *12 (N.D. Cal. Aug. 10, 2005) (no scienter inference where company raised $60 million in a secondary offering two months before alleged corrective disclosure even where financing was needed to keep company a going concern). To

hold otherwise would mean that nearly every development-stage biotechnology company *a fortiori* has a motive to commit fraud.[3]

Moreover, as plaintiffs concede (Opp. at 15 n.6), the individual defendants did not sell *any* Ventrus stock during the Class Period and instead *increased* their Ventrus holdings by 103% (Exh. I at 137; CAC, ¶ 93).[4] This Court has held that increasing one's stock holdings during the class period is dispositive in rejecting motive-based scienter allegations. *MRU Holdings*, 769 F. Supp. 2d at 516. (*See* Op. Brief at 10 (citing cases unchallenged in the Opp.).)

Nor does the CAC sufficiently plead that, in making statements about the prospects of the VEN 309 program, defendants engaged in deliberate wrongdoing or recklessness. *Kalnit*, 264 F.3d at 142 (where motive allegations are lacking, a plaintiff must allege with particularity "circumstances indicating conscious misbehavior by the defendant, though the circumstantial allegations must be correspondingly greater") (citations omitted). Nothing in the CAC or the opposition brief comes close to suggesting that defendants were consciously hiding the truth or otherwise engaged in the type of "extreme departure from the standards of ordinary care" necessary to plead scienter where proof of motive is lacking. *Id.* Although plaintiffs discuss Ventrus' public statements and filings at length, they point to no contemporaneous documents, emails or other communications – either within Ventrus, or between Ventrus and the FDA –

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[3] The fact that Ventrus spent more than $36 million on the VEN 309 program further undermines any motive-based inference of scienter. (Exhs. C at 74, S at 258.) *See Oppenheim Pramerica Asset Mgmt. S.A.R.L. v. Encysive Pharms., Inc.*, 2007 WL 2720074, at *5 (S.D. Tex. Sept. 18, 2007) (no scienter inference where defendants "used a large part of the money it acquired from stock sales to finance the development of [its device], indicating defendants' belief that [the device's] potential as a successful and lucrative product for the company justified the expenditures").

[4] Plaintiffs' reliance on *In re Cardinal Health Inc. Sec. Litig.*, 426 F. Supp. 2d 688, 731 (S.D. Ohio 2008) is misplaced. (Opp. at 15 n.6.) There, the defendant sold stock during the class period and made profits in excess of 600% from his pre-class period sales. *Id.* at 732. Here, defendants held ***all*** of their stock, losing $4.3 million in the value of their holdings by the end of the Class Period.

reflecting facts that contradict defendants' public statements, or showing that defendants were disseminating information that was different from what was otherwise available to them. *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 453, 471 (S.D.N.Y. 2008) (dismissing complaint where "there is nothing to indicate that the statements made did not reflect the honest belief of the authors").

Absent other indicia of scienter, plaintiffs are forced to fall back on a "core operations" inference (Opp. at 13-14), which is not "independently sufficient to raise a strong inference of scienter" when considered "as a part of [the Court's] holistic assessment of the scienter allegations." *Shemian v. Research in Motion Ltd.*, 2013 WL 1285779, at *18 (S.D.N.Y. Mar. 29, 2013); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 326 (2007).

III. PLAINTIFFS FAIL TO PLEAD FALSITY WITH PARTICULARITY

Statements Regarding the Use of IPO Proceeds: Plaintiffs contend defendants "employed a bait and switch tactic" by assuring investors that they planned to use IPO and secondary offering proceeds for VEN 309 when the "true" use was "to stay afloat and to finance the development of VEN 307 and VEN 308." (Opp. at 1, 17.) This is nothing more than a conclusory assertion. It is also pure fiction. Far from only using "some of the proceeds" on VEN 309 (Opp. at 17), Ventrus spent the ***vast majority*** of these proceeds (over $36 million) on VEN 309, which plaintiffs concede was six times more than it spent on VEN 307 and VEN 308 combined (Exhs. C at 74, S at 258; CAC, ¶ 104). It is inexplicable that plaintiffs would allege fraud on this basis in the face of this fact.

Statements Regarding the Phase IIb Study Sample Size: Conceding that "[d]efendants accurately disclosed the [121-patient] sample size of the Phase IIb trial" (Opp. at 20), plaintiffs quizzically claim that this "misses the mark" (*id.* at 19). In fact, this concession is

fatal to plaintiffs' claims. It is now undisputed that, at all relevant times, defendants fully and accurately informed investors of the design and results of the Phase IIb trial – including its sample size. Defendants also disclosed the design and results of all other VEN 309 trials. (*See, e.g.*, Exhs. A at 23-28, C at 48-53, D at 99-104, E at 112, *etc.*) Given plaintiffs' concession that investors had the same information defendants had (the CAC nowhere alleges that defendants possessed any undisclosed VEN 309 data), it is clear that investors and industry analysts were able to make their own independent assessments of the Phase IIb trial results and of VEN 309 in general. How can defendants be accused of fraud when all material information was publicly disclosed? As this Court has held, they cannot. *MRU Holdings*, 769 F. Supp. 2d at 513 ("A complaint fails to state a 10(b) claim when the alleged omission has actually been disclosed.") (citation omitted). It is also telling that plaintiffs nowhere allege that the sample size of the Phase IIb trial was contrary to industry or regulatory standards.[5] To the extent that CW1 has opined in retrospect that the sample size could have been larger, his opinion "merely amount[s] to a competing view of how the trial should have been designed" and is no way indicative of fraud. *Abely v. Aeterna Zentaris, Inc.*, 2013 WL 2399869, at *10 (S.D.N.Y. May 29, 2013).

Statements Regarding an SPA for the Phase III Study: Plaintiffs make the conclusory allegation that defendants pursued an SPA for VEN 309 merely as a means of luring investors without any intention of actually completing the SPA process. (Opp. at 20-21.) The CAC and the opposition brief cite no particularized facts to support this assertion. Instead, they rely solely on CW1's opinion about the perceived effects of SPAs in general, which is completely devoid of any information about the particular SPA process that Ventrus pursued here – largely after CW1 had already left the company. While defendants did not formally complete the SPA process,

[5] As noted in defendants' opening brief, the FDA did not take issue with the Phase IIb sample size when it authorized Ventrus to proceed with the Phase III trial. (*See* Op. Brief at 18.)

they nevertheless adopted all of the endpoints and protocol changes recommended by the FDA. (CAC, ¶ 55; Exh. G at 132.) Thus, contrary to plaintiffs' assertions, there was nothing remotely misleading in defendant Ellison's statement that discussions with the FDA had been "productive" – indeed, they led to the final protocol and endpoints of the Phase III trial.[6] Absent any evidence – or even a factually particularized allegation – indicating that defendants were pursuing an SPA in bad faith, this aspect of the CAC amounts to nothing but sheer speculation.

Statements Regarding Phase III Study Progress: Plaintiffs may now claim ignorance of what a "Severe Adverse Event" is (Opp. at 18), but a reasonable investor of a development-stage biotechnology company cannot. *See* 21 C.F.R. § 312.32(a) (defining "Severe Adverse Event"); *Berry v. Valence Tech, Inc.*, 175 F.3d 699, 703 n.4 (9th Cir. 1999) ("A reasonable investor is presumed to have information available in the public domain . . . .") (citation omitted)). Plaintiffs also claim that defendants delayed the reporting of the Phase III trial results in bad faith so that Ventrus could effect a third stock offering. (Opp. at 19.) Plaintiffs offer no evidence to support this conclusory allegation. In fact, the record (including the same documents that plaintiffs rely on in the CAC) shows the nonculpable reasons for the brief delay in reporting the trial results. (*See* Op. Brief at 20-21 (quoting Exh. K at 171).)[7]

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[6] The final endpoints of the Phase III trial were identical to the endpoints that were the subject of a *post hoc* analysis of the Phase IIb data which yielded highly favorable results. (*See* Op. Brief at 19 (citing CAC, ¶¶ 55, 59, 61, 75; Exh. E at 112).) Plaintiffs do not even address defendants' *post hoc* analysis of the Phase IIb trial. Nor do they make any effort to substantiate their claim that the Phase IIb trial "was far more subjective" than the Phase III trial. As previously noted, both the Phase IIb and the Phase III trials relied on patient-reported (*i.e.*, subjective) outcomes. (Op. Brief at 19 n.15.)

[7] Like the CAC, plaintiffs' opposition brief baldly states that "none of the participants" in the Phase III trial met the efficacy endpoints. (Opp. at 19.) Not so – several of the Phase III trial participants met the primary and secondary efficacy endpoints, just not a statistically significant rate "over placebo." (CAC, ¶ 90.) *See Rapoport v. Asia Elecs. Holding Co.*, 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000) (holding that where the basis of plaintiffs' claims contradict the allegations in a complaint, "the documents control").

IV. MANY OF THE CHALLENGED STATEMENTS ARE NOT ACTIONABLE

Statements of Corporate Optimism: Plaintiffs ignore recent Second Circuit precedent holding that a defendant's "puffery and corporate optimism" do not give rise to securities violations. *See Klienman v. Elan Corp., PLC*, 706 F.3d 145, 153 (2d Cir. 2013) (citation omitted). Further, as explained above and in defendants' opening brief, the CAC pleads no particularized facts showing that defendants' "opinions were both false and not honestly believed when made." *Id.* (*See* Op. Brief at 21-22.)

The PSLRA Safe Harbor and The "Bespeaks Caution" Doctrine: Plaintiffs maintain that statements made in connection with an IPO are not protected by the PSLRA safe harbor for forward-looking statements. (Opp. at 21.) This argument applies to only a small number of the statements at issue, since most of the statements alleged in the complaint post-date the IPO. (CAC, ¶¶ 48-87.) In any event, even if the PSLRA does not, by its terms, provide a statutory safe harbor for statements made in connection with an IPO, courts have fashioned an equivalent doctrine at common law which embraces all forward-looking statements, including those made in connection with IPOs. Specifically, under the "bespeaks-caution" doctrine, the Second Circuit has held that a forward looking statement accompanied by sufficient cautionary language is not actionable because no reasonable investor could have found the statement materially misleading. *See Iowa Pub. Emps. Ret. Sys. v. MF Global, Ltd.*, 620 F.3d 137, 141 (2d Cir. 2010); *P. Stolz Family P'ship L.P. v. Daum*, 355 F.3d 92, 96-97 (2d Cir. 2004). The Second Circuit uses the same analysis regardless of whether the "bespeaks-caution" doctrine or the PSLRA safe harbor applies. *Id.* Under that analysis, all challenged statements here were inactionable forward-looking statements accompanied by meaningful risk warnings that were custom-tailored to the VEN 309 program and described precisely what happened here. *See Const. Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, 2008 WL

2053733, at *10 (S.D. Cal. May 13, 2008) (applying safe harbor where "warnings explained the precise risk which materialized").

V. PLAINTIFFS' SECTION 20(A) CLAIM MUST BE DISMISSED

Plaintiffs do not dispute that a failure to plead a Section 10(b) claim precludes a claim under Section 20(a). *See Slayton v. Am. Exp. Co.*, 604 F.3d 758, 777-78 (2d Cir. 2010). Since plaintiffs' Section 10(b) claim fails, so too does their Section 20(a) claim.

VI. CONCLUSION

For the reasons discussed here and in the Opening Brief, the CAC should be dismissed.

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